

Md. Appeals Court Slams Researchers

Participants in Study on Lead Paint Weren't Informed of Risks, Judge Says

By Manuel Roig-Franzia and Rick Weiss
Washington Post Staff Writers
Tuesday, August 21, 2001; Page B01

The Maryland Court of Appeals' sweeping condemnation of lead paint researchers at Baltimore's Kennedy Krieger Institute has reinforced the rights of research subjects to know the risks they face, while tainting the prestigious research center by comparing its work to the infamous Tuskegee, Ala., experiments that withheld treatment to black men infected by syphilis.

The court could have limited its remarks to a narrow legal question about a Kennedy Krieger study that exposed poor infants to lead paint and lead dust in the mid-1990s. Instead, the court took the extraordinary step of issuing a scathing 98-page opinion that broadly admonished research methods in the state and accused the Johns Hopkins University board that oversaw the study of purposely misleading participants about the dangers involved.

"It can be argued that the researchers intended that the children be the canaries in the mines, but never told the parents," Judge Dale R. Cathell wrote.

The ruling, issued Thursday, stemmed from lawsuits filed by parents of two children against Kennedy Krieger, a Baltimore children's hospital and research center whose lead paint study was overseen by Johns Hopkins University.

A Kennedy Krieger spokeswoman declined to comment on the ruling but issued a statement that said 25 years of research at the institute have "resulted in proven ways to help reduce the problem of childhood lead poisoning and [have] benefited children and families by reducing their exposure to lead."

Last month, regulators briefly shut down all federally funded human research at Hopkins, citing several shortcomings in its institutional review boards, which oversee medical studies at the university. The shutdown, which lasted five days and affected hundreds of clinical trials involving more than \$300 million, was prompted by the June 2 death of a healthy young volunteer in a Hopkins asthma study.

In the lead paint study ruling, Cathell described the Johns Hopkins Institutional Review Board as a nonobjective "house organ" and questioned whether "the scientific and medical communities" should have sole authority to oversee studies involving children. The board instructed researchers to rewrite consent forms to get around federal regulations designed to protect human research subjects, Cathell wrote.

"This is an extremely important decision," said Alan Milstein, a lawyer from Pennsauken, N.J., who has defended human research subjects in several recent high-profile cases. "It says, 'If you have an unethical experiment, just because someone agreed to it does not turn it into an ethical experiment.'"

The Kennedy Krieger lead paint study was designed to find cheaper techniques for removing lead paint so that Baltimore landlords who had complained about high abatement costs would not abandon many of the city's signature row houses in low-income neighborhoods, Cathell's opinion said.

Landlords participating in the study were encouraged by researchers to rent to families with small children because the young are more susceptible to lead poisoning, Cathell wrote.

The 108 families recruited for the study were separated into four groups. One of the groups lived in homes that had undergone complete lead abatement, Cathell wrote. The other three groups lived in homes that received lesser levels of abatement, ranging from minimal work costing \$1,650 to more extensive work costing \$6,000 to \$7,000, Cathell wrote.

Researchers, who conducted regular blood testing, gave out incentives, such as T-shirts, food stamps, \$5 payments for parents who submitted to interviews and \$15 for filling out questionnaires, Cathell wrote.

"Otherwise healthy children, in our view, should not be enticed into living in, or remaining in, potentially lead-tainted housing," Cathell wrote.

The ruling was prompted by the decisions of two Baltimore judges -- Allen Schwait and Stuart Berger -- to dismiss separate lawsuits filed by the parents of Ericka Grimes and Myron Higgins without holding trials.

Researchers withheld test results that showed high lead levels at Ericka's home for nine months, and by then, she had lead poisoning, Cathell wrote. Ericka, who was 10 months old when the study started, now suffers from learning disabilities and cognitive impairments, both of which are often associated with lead poisoning, according to her mother's attorney, Kenneth W. Strong.

Myron was 3 1/2 years old in May 1994 when his mother, Catina Higgins, rented a \$315-a-month apartment that had undergone a medium-level lead abatement one month earlier. Catina Higgins accused researchers of giving her a "false sense of security" by disclosing to her test results that showed low levels of contamination but withholding results that showed high levels.

The mothers signed consent forms that did not disclose all the dangers involved in the study, Cathell wrote, reversing the lower court's finding that Kennedy Krieger had no legal obligation to inform them about the dangers.

Court of Appeals Judge Irma S. Raker agreed with the decision to order trials in the lawsuits but refused to concur with Cathell's opinion that the lead paint study was comparable to the Tuskegee experiment or that the children's health was put at risk. Chief Judge Robert M. Bell recused himself from the case because he is on the Hopkins board and was replaced by retired judge Robert L. Karwacki.

The study was conducted by Marc Farfel with a \$200,000 grant from the U.S. Environmental Protection Agency. The Maryland Department of Housing and Community Development was a co-sponsor, and the Baltimore City Health Department and the Maryland Department of the Environment were collaborators.

© 2001 The Washington Post Company